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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,339	08/19/2003	Jiajiu Shaw		3776

7590 12/10/2004  
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EXAMINER	
NAZARIO GONZALEZ, PORFIRIO	
ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/643,339	Applicant(s) SHAW, JIAJIU	
	Examiner Porfirio Nazario-Gonzalez	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Priority*

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 3 and 5-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of carcinoma of the uterus, does not reasonably provide enablement for the treatment of all the types of cancer recited on claims 3 and 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is clear from the instant specification that the claimed compounds and pharmaceutical compositions show activity against the carcinoma of the uterus UFX 1139L (in-vitro studies). What is not clear is the extrapolation of these results to cover the treatment of other types of cancer without any experimental data that would support such conclusions. Further, the same compound and pharmaceutical composition (containing the compound in the instant example 2) was found to be inactive against five human ovarian carcinoma cell lines. See Jolley et al., *Journal of Inorganic Biochemistry*, Vol.83, pp. 91-100 (2001), particularly page 99, column 1, first paragraph, last sentence. This supports the Examiner's argument that extrapolating from a single example to embrace a long list of types of cancer without providing any experimental data is not enable for that list.

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4. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant statement on page 9, first paragraph, “of the potential ability of these complexes to hamper the DNA or RNA replication process, it is conceivable that these complexes are effective against the HIV...” of the instant specification does not enable claim 17. This statement does not support the conclusion that said complexes have anti-virus activity without any experimental data to support it. The anti-cancer properties against the carcinoma of the uterus do not lend support to the argument that said compounds also have anti-virus properties. Further, the words “potential” and “conceivable” are not statements of fact but of possibility, and, possibilities require experimentation to ascertain whether that possibility is actually a fact. Thus, one skill in the art would not be able to use and/or make the instant invention without undue experimentation.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

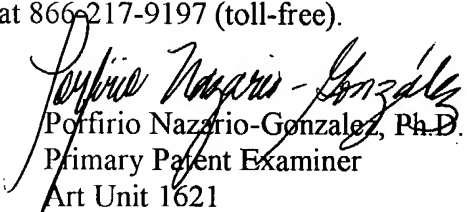
6. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jolley et al., Journal of Inorganic Biochemistry, Vol.83, pp. 91-100 (2001). The Jolley et al. reference discloses a platinum (II) complex having ethylenediamine-derived ligands having a carboxylic acid substituent. See compound (5) on page 93 and Table 3 on page 97.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Porfirio Nazario-Gonzalez whose telephone number is 571-272-0641. The examiner can normally be reached on Mon.-Fri. (9:30 AM - 6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Porfirio Nazario-Gonzalez, Ph.D.  
Primary Patent Examiner  
Art Unit 1621

PNG

December 8, 2004